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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER
	28

DATE MAILED: 10/09/96

This is a communication from the examiner in charge of your application.
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OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 5/30/95.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 25-27 & 42 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 25-27 & 42 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. No substantive response has been filed to the Office action mailed on 30 December 1994 (Paper No. 23) in parent application 08/260,203.

Claim Rejections - 35 USC § 112

3. Claims 25-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for PDGF AA homodimers having the native sequence shown in Figures 1 and 2, does not reasonably provide enablement for analogs of PDGF AA which are substantially homologous and functionally equivalent to PDGF AA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record set forth in Paper No. 5, pages 5-6 and Paper No. 8, pages 2-5.

4. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 recites a PDGF A chain polypeptide comprising the amino acid sequence from positions 1-86, which define the signal sequence and propeptide of the precursor form of the PDGF A chain, while the specification states that the PDGF A chain consists of at least amino

acids 87-193 (p. 6). Therefore, it is unclear whether what is being claimed is a polypeptide including at least amino acids 1-193, that is, the signal sequence and propeptide of PDGF A (amino acids 1-86) along with PDGF A itself (amino acids 87-193), or whether what is claimed is a polypeptide which may include only amino acids 1-86, which encompasses only the signal sequence and propeptide of PDGF A, and not the PDGF A molecule itself. For the purposes of examination, the claim will be interpreted to include at least amino acids 1-193 of PDGF A. If the latter interpretation is intended, Applicant is advised that issues of new matter and enablement would be raised.

Claim Rejections - 35 USC § 102

5. Claims 25-27 and 42 are rejected under 35 U.S.C. 102(a) as being anticipated by Betsholtz et al. (Nature 320, 695-699, 1986).

Betsholtz teaches the amino acid sequence of PDGF A chain, including both the precursor form of PDGF A, which comprises the amino acid sequence depicted at positions 1-86, as well as the mature form of the protein which encompasses amino acid residues 87-211 (Fig. 2, p. 697). Furthermore, Betsholtz discloses a purified PDGF AA, which is a disulfide-linked homodimer secreted by human tumor cells (p. 698 and Fig. 4, p. 699). Although Betsholtz does not disclose a recombinant PDGF AA homodimer, as recited, a product by process limitation for a composition is considered only insofar as it alters the composition. In the absence of evidence to the contrary, the recombinant protein of claims 25-27 is considered identical to the prior art protein purified from nature, as disclosed by Betsholtz.

6. Claims 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Murray et al. (U.S. Pat. No. 4,889,919).

Murray teaches the amino acid sequence of the PDGF A chain (Fig. 9) and a recombinantly produced form of PDGF AA (Example VIII, col. 27, line 31 to col. 28, line 34). Murray further discloses that the protein is a disulfide-linked homodimer (col. 25, lines 1-26). Although the PDGF A chain taught by Murray consists of only 104 amino acids, corresponding to amino acid sequence 87-190 of the PDGF A chain of the instant application, the amino acid sequence of those 104 amino acids are identical to that of the instant application and the PDGF AA homodimer has mitogenic activity (col. 28, line 35 to col. 29, line 15), such that the PDGF AA homodimer taught by Murray is substantially homologous and functionally equivalent to the PDGF AA claimed in the instant application, and thus is deemed to meet the limitations of the instant claims, absent evidence to the contrary.

7. Claims 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Heldin et al. (Nature 319, 511-514, 1986).

Heldin teaches a PDGF AA homodimer derived from ostesarcoma cells which is disulfide linked (p. 511, col. 2). Although the entire amino acid sequence of the PDGF AA homodimer was not determined, N-terminal sequencing of the homodimer yielded a sequence which was identical to the N-terminal sequence of the A chain of PDGF (p. 512). Although the exact number of amino acids in each A chain was not determined, as recited in the instant claims, Heldin discloses that the purified PDGF AA had agonist activity and was recognized by antibodies

against PDGF (p. 511), such that the PDGF AA taught by Heldin is substantially homologous and functionally equivalent to the PDGF AA claimed in the instant application, and thus is deemed to meet the limitations of the claims, absent evidence to the contrary. Furthermore, although Heldin does not disclose a recombinant PDGF AA homodimer, as recited, a product by process limitation for a composition is considered only insofar as it alters the composition. In the absence of evidence to the contrary, the recombinant protein of claims 25-27 is considered identical to the prior art protein purified from nature, as disclosed by Heldin.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Karen E. Brown at (703) 308-3667, fax number (703) 308-0294. The Examiner can normally be reached Mondays through Thursdays and alternate Fridays from 7:30 a.m. to 5:00 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Stephen Walsh, can be reached at (703) 308-2957.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist at (703) 308-0196.

KEB

Karen E. Brown
8 October 1996

Stephen Walsh
STEPHEN G. WALSH
PRIMARY EXAMINER
GROUP 1800